Centers for Medicare & Medicaid Services

[Document Identifier: CMS-368 and -R-144]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically*. You may send your comments electronically to http://www.regulations.gov. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. By regular mail. You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number:

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at

https://www.cms.gov/Regulations-and-

Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786-4669. **SUPPLEMENTARY INFORMATION:**

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-368 and -R-144 Medicaid Drug Rebate Program State Reporting Forms

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the <u>Federal Register</u> concerning each proposed collection of information, including each proposed extension or reinstatement of an

existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Medicaid Drug Rebate Program State Reporting Forms; Use: Form CMS 368 is a report of contact for the State to name the individuals involved in the Medicaid Drug Rebate Program (MDRP) and is required only in those instances where a change to the originally submitted data is necessary. The ability to require the reporting of any changes to these data is necessary to the efficient operation of these programs. Form CMS-R-144 is required from States quarterly to report utilization for any drugs paid for during that quarter.

While there are no changes to the CMS-R-144 form, we propose non-substantive verbiage updates to the corresponding CMR-R-144 File Format and corresponding Data Definitions. Form CMS-368 has been revised to include a signature/date line for the submitter to confirm that the information provided is accurate. We have also updated the entire CMS-368 form to a fillable format. We also propose to remove the one-time system update burden that was added in the last iteration of this collection of information request.

Form Number: CMS-368 and -R-144 (OMB control number: 0938-0582); Frequency: Quarterly and on occasion; Affected Public: State, Local, or Tribal Governments; Number of Respondents: 56; Total Annual Responses: 234; Total Annual Hours: 12,325. (For policy questions regarding this collection contact Andrea Wellington at 410-786-3490.)

Dated: November 5, 2021.

Martique Jones,

Director,

Regulations Development Group,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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